PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P 03 134 WO	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/DK2005/000104	International filing date *(day/month/year)* 17.02.2005	Priority date *(day/month/year)* 18.02.2004
International Patent Classification (IPC) or national classification and IPC A61M5/158		
Applicant UNOMEDICAL A/S et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
15.09.2005	16.01.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Björklund, A Telephone No. +49 89 2399-

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2005/000104

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-9 as originally filed

Claims, Numbers

1-13 as originally filed

Drawings, Sheets

1/3-3/3 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-13
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-13
Industrial applicability (IA)	Yes:	Claims	1-13
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US 2002/123740 A1 (FLAHERTY J CHRISTOPHER ET AL) 5 September 2002 (2002-09-05)

D2: WO 02/081012 A (DISETRONIC LICENSING AG ; DENOTH PATRIK (CH); HUNN MARCEL (CH); LINIGE) 17 October 2002 (2002-10-17)

D3: US-A-4 755 173 (KONOPKA APRIL A ET AL) 5 July 1988 (1988-07-05)

D4: US-B1-6 572 586 (WOJCIK STEVEN E) 3 June 2003 (2003-06-03)

D5: DE 201 14 795 U (DISETRONIC LICENSING AG) 7 February 2002 (2002-02-07)

D6: US 2003/069542 A1 (MENG CLEMENT WAN CHYE ET AL) 10 April 2003 (2003-04-10)

D7: WO 03/020360 A (DISETRONIC LICENSING AG; REINMANN, ANDREAS; HUNN, MARCEL) 13 March 2003 (2003-03-13)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-13 is not new in the sense of Article 33(2) PCT.

2.1. The document D1 discloses (the references in parentheses applying to this document):

Infusion device for subcutaneous administering a medication or a therapeutic fluid to a patient, comprising

a base element (fig. 24, item 222), comprising

fluid receiving means for receiving said fluid,

fluid communication means for transferring said fluid into a cannula (item 260), and

at least one recess for accommodating a septum (item 241) pierceable by a needle; and

a septum housing accommodating the septum;

wherein the septum is secured to the base element by the septum housing in such a way that a fluid transfer volume is formed in said at least one recess between an internal surface of the septum and an inner section of the recess in the base element,

said fluid transfer volume communicating with the fluid connection means (fig. 24, the part outside the septum 241 is a septum housing),

wherein
the septum is radially compressed in the septum housing so that a fluid-tight seal is provided between the septum and the septum housing, as well as between the septum housing and the base element (implicit, as the septum must be held by a radial compression in the septum housing).

The subject-matter of claim is therefore not new (Article 33(2) PCT).

2.2. The embodiment on figs. 22-23 and described in [0099] of D1 discloses the features of claim 1. Moreover, also the documents D2-D7 (e.g. D2, fig. 3, items 1-5; D3, figs. 2 & 5, items 14, 48, 52, 54 & 56, col. 8, lines 18-31; D4, fig. 5, items 12, 16, 52 & 54; D5, fig. 2, items 2, 5, 8 & 10; D6, figs. 1-11, items 24, 27 & 29, [0032]-[0033]; D7, figs. 2-5, items 2, 4, 15 & 20, page 8, last paragraph - page 9, first paragraph) disclose the features of claim 1 (Article 33(2) PCT).

3. Dependent claims 2-13 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, for the following reasons:

Claims 2-13 merely define trivial design options for the device, such as the connection of the cannula, and different ways of connecting the septum and the septum housing to the base element which are known in the art of infusion devices, see documents D1-D7 and the corresponding passages cited in the search report. Furthermore, these options do not seem to present any surprising technical effects.

Re Item VII
Certain defects in the international application

4. None of the claims are provided with reference signs (Rule 6.2(b) PCT).

5. Documents D1-D3 are not mentioned in the description (Rule 5.1(a)(ii) PCT).

Re Item VIII
Certain observations on the international application

6. The embodiments on figs. 6-8 do not fall under the scope of claim 1. It should therefore have been made clear that they do not form part of the invention (Article 6 PCT).